

## CODE: VORINOSTAT

[Regimen Name](#) | [Drug Regimen](#) | [Cycle Frequency](#) | [Premedication & Supportive Measures](#) | [Dose Modifications](#) | [Adverse Effects](#) | [Interactions](#) | [Drug Administration & Special Precautions](#) | [Clinical Monitoring](#) | [Administrative Information](#) | [Key References](#) | [Other Notes](#)

A REGIMEN NAME		
<b>Cancer</b>	Cutaneous T-cell Lymphoma (CTCL)	Palliative intent
<b>Regimen Category</b>	<b>Core:</b> standard therapy endorsed by the Disease Site Group and a regimen widely used by most integrated cancer programs in this disease site.	
<b>Rationale and Uses</b>	Treatment of cutaneous manifestations in patients with advanced cutaneous T-cell lymphoma (CTCL) who have progressive, persistent or recurrent disease after prior systemic therapies	

▲ [Back to Top](#)

B DRUG REGIMEN			
<b><u>VORINOSTAT</u></b> (outpatient prescription in 100 mg capsules)	400 mg	PO	Daily (with meal)

▲ [Back to Top](#)

C CYCLE FREQUENCY	
<b>CONTINUOUS TREATMENT</b>	<i>Until disease progression or unacceptable toxicity.</i>

▲ [Back to Top](#)

D PREMEDICATION AND SUPPORTIVE MEASURES	
<b>ANTIEMETIC REGIMENS:</b> <b><u>HESKETH LEVEL 1</u></b>	<i>Patients should be instructed to drink at least 2 L/day of fluids for adequate hydration</i>

▲ [Back to Top](#)

**E DOSE MODIFICATION**

Doses should be modified according to the protocol by which the patient is being treated. The following recommendations are in use at some centres.

See [Appendix 6](#) for general recommendations.

Suggested dose levels are 400 mg daily, 300 mg daily, and 300 mg daily for 5 consecutive days per week.

Toxicity	Action	Dose
Grade 3	Hold <sup>#/*</sup>	↓ 1 dose level
Grade 4	Hold <sup>#</sup> ; or discontinue	If re-start, ↓ 1 dose level

\* consider hold for Platelets 10-25 x 10<sup>9</sup>/L and/or Hemoglobin 65-80 g/L if considered related to vorinostat.  
<sup>#</sup> until recovery to ≤ grade 1

Renal Impairment:

No data available. Treat with caution in renal impairment as the 2 major metabolites are excreted in urine.

Hepatic Impairment:

Bilirubin	Action
1.5 – < 3 X ULN	<b>Discontinue</b> ; not recommended for use
≥ 3 X ULN	<b>CONTRAINDICATED</b>

[▲ Back to Top](#)

**F ADVERSE EFFECTS**

Refer to Vorinostat drug monograph for full details of adverse effects.

Most Frequently Occurring Adverse Effects

- Nausea, vomiting, diarrhea (may lead to dehydration)
- Fatigue
- Taste disturbance
- Thrombocytopenia, anemia (may be severe)
- Anemia (may be severe)
- Hyperglycemia
- Increased creatinine, proteinuria (usually mild to moderate)

**F****ADVERSE EFFECTS (Continued)**Less common but may be Severe or Life-Threatening

- Arterial and venous thromboembolism
- QT prolongation, increase in heart rate

▲ [Back to Top](#)

**G****INTERACTIONS**

Refer to Vorinostat drug monograph for full details.

▲ [Back to Top](#)

**H****DRUG ADMINISTRATION AND SPECIAL PRECAUTIONS**

Refer to Vorinostat drug monograph for full details.

▲ [Back to Top](#)

**I****CLINICAL MONITORING**

- Routine clinical toxicity assessment of dehydration, hyperglycemia, fatigue, gastrointestinal, and cardiovascular toxicities. Grade toxicity using the current [NCI Common Toxicity Criteria Version](#)
- Baseline CBC, electrolytes (including Ca, Mg, K) and blood glucose, then every 2 weeks during the first 2 months of therapy and monthly thereafter
- Baseline and periodic ECGs
- Baseline and routine liver and renal function tests

▲ [Back to Top](#)

**J** ADMINISTRATIVE INFORMATION

Outpatient prescription for home administration.

▲ [Back to Top](#)

**K** KEY REFERENCE(S)

Duvic M, Talpur R, Ni X, et al. Phase 2 trial of oral vorinostat (suberoylanilide hydroxamic acid, SAHA) for refractory cutaneous T-cell lymphoma (CTCL). *Blood* 2007; 109: 31-9.

Olsen EA, Kim YH, Kuzel TM, et al. Phase IIB multicenter trial of vorinostat in patients with persistent, progressive, or treatment refractory cutaneous t-cell lymphoma. *J Clin Oncol* 2007; 25: 3109-15.

▲ [Back to Top](#)

**L** OTHER NOTES

Vorinostat is not listed in the the Ontario Drug Benefit Formulary.  
Prescription costs may be covered by some third party insurance plans.

▲ [Back to Top](#)

April 2010: Modified sections A and L